

REMARKS

In the present communication, claim 1 has been amended; claims 43 and 44 have been added; and no claims have been canceled. The amendments and new claims do not add new matter and are fully supported throughout the specification and claims as filed as discussed below. Accordingly, upon entry of the present amendment, claims 1, 3-10, 12-14, 16-18, 39 and 42-44 will be pending and at issue.

Amendments to the Claims

Various amendments have been made to the claims as provided herein. The amendments are fully supported throughout the specification and claims as filed and do not add new matter. Support for the amendments are provided below as identified in the application as published in U.S. Patent Application Publication 2006/0151900.

Claim 1 has been amended to clarify that the solution is maintained below saturation. Support for the amendment may be found throughout the specification, for example, in paragraphs [0077] and [0100] of the specification. This assists in avoiding blockages in the spray nozzle. (See end of paragraphs [0077] and [0100] of the specification). Thus the molten homogeneous solution is advantageously less viscous. (See paragraphs [0049] and [0050] of the specification).

New claim 43 is identical to amended claim 1, with the exception that new claim 43 further recites the limitation of claim 3. For instance, new claim 43 recites that the carrier fluid is the same as the liquefied gas or dense gas. Accordingly, support for new claim 43 may be found in originally filed claim 3 as well as throughout the specification, for example, in paragraphs [0077] and [0100] of the specification.

New claim 44 is identical to amended claim 1, with the exception that new claim 44 further recites the limitation of claim 3 and additionally recites that the contacting step is performed at constant temperature and pressure. Support for new claim 44 may be found in

originally filed claim 3 as well as throughout the specification, for example, in paragraphs [0016], [0077], and [0100] of the specification.

Rejections under 35 U.S.C. §103

Applicants respectfully traverse the rejection of claims 1, 3-6, 8-12, 39 and 42 under 35 U.S.C. §103(a) as allegedly being obvious over Kerč et al. (*International Journal of Pharmaceuticals*, 182:33-39 (1999); hereinafter “Kerč”) in view of Kropf et al. (U.S. Patent No. 6,316,030; hereinafter “Kropf”), Jung et al. (*Journal of Supercritical Fluids*, 20:179-219 (2001); hereinafter “Jung”), and Weidner et al. (U.S. Patent No. 6,056,791; hereinafter “Weidner”).

The U.S. Supreme Court decision in *KSR International v. Teleflex Inc.* (82 USPQ2d 1385), modified the standard for establishing a *prima facie* case of obviousness. Under the *KSR* rule, three basic criteria are considered. First, some suggestion or motivation to modify a reference or to combine the teachings of multiple references still has to be shown. Second, the combination has to suggest a reasonable expectation of success. Third, the prior art reference or combination has to teach or suggest all of the recited claim limitations. Factors such as the general state of the art and common sense may be considered when determining the feasibility of modifying and/or combining references.

The Office Action acknowledges that Kerč fails to disclose a number of elements of the method of claim 1. For example, the Office Action acknowledges that Kerč fails to teach: 1) a method utilizing a liquefied gas or dense gas to melt a solid substance; 2) a pressure chamber having an outlet that is above an inlet; 3) use of a carrier fluid at the same pressure as the liquefied gas to pass the molten homogeneous solution out through the outlet; and 4) a method in which the carrier fluid is passed through the solution. The Office Action requires Kropf, Jung and Weidner to attempt to remedy the deficiencies.

Applicants assert that in determining the differences between the prior art and the claims, the question is not whether the differences themselves would have been obvious, but whether the

claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983). Distilling an invention down to the "gist" or "thrust" of an invention disregards the requirement of analyzing the subject matter "as a whole." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

As discussed throughout the specification, the claimed method encompasses a configuration in which complications of the prior art process termed 'Particles from Gas Saturated Solutions' (PGSS) are solved. For example, the configuration in which the inlet is disposed beneath the outlet, as claimed, "is to deliberately keep the liquefied gas or dense gas solution below saturation. This assists in avoiding blockages in the 50 micron nozzle." See, end of paragraph [0077] of the specification. Thus the molten homogeneous solution is advantageously less viscous (see paragraphs [0049] and [0050] of the specification) as compared with previously known PGSS processes. The reduced viscosity assists in preventing blockage of the outlet nozzle.

Without acquiescing to the reasoning presented in the Office Action, and in order to expedite prosecution of the instant application, Applicants have amended claim 1 to further clarify that the solution is maintained below saturation. As discussed above, this is to prevent blockage of the nozzle upon depressurization. Applicants assert that Kerč, Kropf, Jung, and Weidner all fail to disclose the claimed limitation. Further, the cited references fail to appreciate the complication of nozzle blockage resulting from the solution being completely saturated, and more importantly fail to disclose any solution. As the references fail to teach each and every element of the claimed invention and further provide no motivation for modifying the devices disclosed in the cited references to maintain the solution below saturation, no *prima facie* case of obviousness has been established. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

With regard to new claim 43, in addition to the newly added limitation to claim 1 discussed above, claim 43 further recites that the carrier fluid is the same as the liquefied gas or

dense gas. While acknowledging the Kerč fails to teach the recited limitation, the Office Action alleges that since Kerč discloses the carrier fluid as optional (citing page 34, section 2.2, line 3) and discloses the liquefied gas acting as a carrier fluid by carrying the drug into the expansion chamber, it would have been obvious to use the same gas as the liquefied gas and the carrier fluid. Applicants note that the line referenced in the Office Action states that “[I]n the PGSS process (Fig. 1), a compressible gas (i.e. CO₂) is dissolved under pressure in a melted drug (or a mixture of drug/carrier).” Page 34, section 2.2, line 3. Applicants assert that the passage has been misconstrued in that reference to the carrier is in regard to a mixture of drug and drug carrier (e.g., substances that serve as mechanisms to improve the delivery and the effectiveness of drugs) as opposed to carrier fluid as utilized in the claimed method.

With regard to the assertion that Kerč discloses the liquefied gas acting as a carrier fluid by carrying the drug into the expansion chamber, the reference states only that “[A]fter reaching the equilibrium (approximately 2 h) the gas saturated solution is expanded through the nozzle...and the compressible gas evaporated in the expanding chamber causing the micronization of drug particles.” However, Kerč fails to specifically disclose introduction of additional carrier fluid after a molten solution is formed in the pressure chamber or autoclave as claimed.

With regard to new claim 44, in addition to the newly added limitation to claims 1 and 43 discussed above, claim 44 further recites that the contacting step is performed at constant temperature and pressure. As such, it is clear that the contacting step is performed under isobaric and isothermal conditions. For example, as exemplified in Figure 2 of the specification, the apparatus upstream of the depressurization nozzle is maintained at a constant temperature via a water bath such that all fluid within the conduits and pressure vessel is maintained at the same temperature to ensure isothermal and isobaric conditions upon introduction of the carrier fluid into the pressure chamber.

While acknowledging the Kerč fails to teach use of a carrier fluid at the same pressure as the liquefied gas to pass the molten solution out thought outlet, the Office Action points to

Weidner as remedying the deficiency. The passage relied upon in Weidner recites that “[I]n order to avoid a fall in pressure in the autoclave during the spray process, fresh, preheated gas is metered into the top of the autoclave 24 by the high-pressure pump 28.” Column 8, lines 18-21. However, Weidner fails to disclose that both temperature and pressure are maintained as constant as the carrier fluid is introduced into the pressure chamber to produce isothermal and isobaric conditions as claimed.

It is axiomatic that one cannot simply use the Applicants’ disclosure as a “blueprint” to reconstruct, by hindsight, Applicants’ claim. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 227 U.S.P.Q. 543 (Fed. Cir. 1985). As the cited references fail to disclose each and every element of the claims, nor is there provided motivation to modify the references to arrive at the claimed invention, no *prima facie* case of obviousness exists. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Applicants respectfully traverse the rejection of claims 7, 14 and 16-18 under 35 U.S.C. §103(a) as allegedly being obvious over Kerč in view of Kropf as applied to claims 1 and 6, and further in view of Zhu et al. (US 2002/0110526; hereinafter “Zhu”).

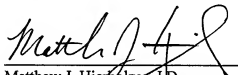
As discussed above, without acquiescing to the reasoning presented in the Office Action, and in order to expedite prosecution of the instant application, Applicants have amended claim 1, from which the rejected claims depend, to further clarify that the solution is maintained below saturation. As discussed above, both Kerč and Kropf fail to disclose the newly recited element. Furthermore, Zhu fails to remedy the deficiencies of Kerč and Kropf as it also fails to disclose the newly recited element. Accordingly the Office Action fails to present a *prima facie* case of obviousness since the cited references, alone or in combination, fail to teach each and every element of the claimed invention. Accordingly, withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

The Commissioner is hereby authorized to charge the total amount of \$425.00 to cover the payment of an Information Disclosure Statement (\$180.00) and a Two-Month Extension of Time fee (\$245.00), small entity to Deposit Account No. 07-1896. No other fees are deemed necessary with the filing of this paper. However, the Commissioner is further authorized to charge any additional fees, or credit any overpayments, to Deposit Account No. 07-1896 referencing the above-identified docket number.

Respectfully submitted,



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